

## Kaczmarek, Chris

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**From:** Taub, Cynthia <CTaub@steptoe.com>  
**Sent:** Monday, November 03, 2014 8:20 AM  
**To:** Talbert, Stephanie (ENRD)  
**Cc:** Goldberg, Seth; Jain, Komal (Komal\_Jain@americanchemistry.com); Allison\_Starmann@americanchemistry.com; Kaczmarek, Chris; Ross, Philip  
**Subject:** Confidential Settlement Communication re Draft Settlement Agreement  
**Attachments:** ENV\_DEFENSE-#696592-v1-ACC\_Settlement\_Agreement\_9\_29\_14.DOC

Stephanie-

Thank you for taking the laboring oar on drafting this settlement agreement. We believe this is a strong start, and we have very few questions or suggested changes. As you can see from the attached redline, our comments are limited to some of the new material in the settlement agreement that we had not previously reviewed, such as the new definitions of "food", "indirect food" and "nonfood", and the new language in paragraph 14 that relates to Chris's email on discussions with AD on issues outside the settlement.

We have concerns about the suggestion in Chris's email (and paragraph 14) that ACC would limit its future claims if EPA fails to meet its obligations under the Agreement. We have never previously discussed such a "release" and do not believe it is necessary or appropriate. First, while ACC has agreed that the 5 issues listed are outside of the **settlement**, ACC does not agree that all 5 of the issues are outside of 158W. For example, the down the drain issue is very much a part of 158W. However, ACC is agreeing to drop **all** of its potential claims regarding the final 158W rule in the proposed settlement agreement. Thus, there will be **no** litigation regarding the final 158W rule as long as the settlement agreement is complied with. However, if EPA fails to meet its obligations under the agreement, reinstating the litigation is the only remedy that ACC will have. In that unlikely case, ACC will no longer be bound by the settlement agreement and it will be up to ACC to determine the scope of its rule challenge at that time. Of course, the court would only entertain claims that are based on the 158W rule, so any issues that are not based on the final rule would not be entertained by the court. In other words, there is a legal restraint on ACC raising any issues in a rule challenge that are not based on the rule itself, including any post-rule discussions with the Agency. Therefore, we do not agree that such a release is appropriate or necessary, and believe the settlement agreement should be amended to strike the last two sentences of paragraph 14.

In terms of next steps, we believe it would be worthwhile to have a final settlement meeting/conference call to talk through our limited comments on the agreement. In addition, we would like clarification as to the expected timing and content of the letter regarding EPA's commitment to provide a comment period for future substantive changes to the USI.

Please let us know some times that work for your team, so that we can work out these final issues and finalize the agreement.

Best,

Cynthia

Cynthia L. Taub  
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## SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into by American Chemistry Council, Inc. ("ACC") and the United States Environmental Protection Agency ("EPA") (together, "the Parties").

### RECITALS

- A. On May 8, 2013, EPA issued a final rule entitled, "Data Requirements for Antimicrobial Pesticides." 78 Fed. Reg. 26,936 (May 8, 2013) ("Final Rule").
- B. On July 3, 2013, ACC filed a petition for review of the Final Rule in *American Chemistry Council, Inc. v. Environmental Protection Agency*, No. 13-1207 (D.C. Cir.).
- C. On July 29, 2013, the Parties jointly filed a motion to hold the petition for review in abeyance in order to pursue settlement discussions. The motion was granted on July 30, 2013, and joint status reports subsequently have been filed pursuant to Court order.
- D. This Agreement resolves all issues related to the Final Rule that ACC raised or could have raised in ACC's petition for review. The Parties have negotiated in good faith and have determined that the settlement of the petition for review without further litigation and through this Agreement is in the public interest.

### AGREEMENT

- 1. Within four months of this Agreement becoming final pursuant to paragraph 9, EPA shall post a proposed guidance document called the Antimicrobial Pesticide Use Site Index ("USI") on the EPA website and take comment on the proposed USI for thirty days.
- 2. EPA shall include in the proposed USI the following descriptions:
  - o Direct Food Use: a use is generally considered to be a direct food use if an antimicrobial pesticide is intended to be directly applied to food and/or food sources, or applied to a material or article for the purpose of treating food.
  - o Indirect Food Use: a use is generally considered to be an indirect food use if the use involves application of the antimicrobial pesticide in or on a material or article that comes into contact with food and results in residues on food, but the use is not intended for pesticidal treatment of food.
  - o Nonfood Use: A use is generally considered to be a nonfood use when there is no reasonable expectation of residues in or on food, for example because the antimicrobial pesticide is not expected to come into contact (directly or indirectly) with food and/or food sources as a result of its intended use.

Commented [A1]: Should we reference the FDCA definition of "food"?

Commented [A2]: What does "food source" mean?

Commented [A3]: What is this clause intended to cover?

Commented [A4]: How will this be defined/determined?

EPA may elaborate on these descriptions in the proposed USI either by referencing specific uses that fall into each of these categories or by otherwise further illustrating what the descriptions mean.

3. EPA shall consider any comments submitted and subsequently post on the EPA website the USI with any changes that EPA deems appropriate within six months of the end of the thirty-day comment period.
4. Within two years and six months of this Agreement becoming final pursuant to paragraph 9, EPA shall propose a correction to the Final Rule that will make the language of the Final Rule as it pertains to the 200 ppb level established in 40 C.F.R. § 158.2230(d) consistent with the U.S. Food and Drug Administration's use of that same level by making clear that the 200 ppb level established in the Final Rule is based on total estimated daily dietary intake, and is not based on the amount of residue present on only a single commodity.
5. Within sixty days of this Agreement becoming final pursuant to paragraph 9, EPA shall issue an interim guidance document explaining EPA's interpretation of the 200 ppb level established in the Final Rule.
6. The Parties may, by written mutual agreement, extend the dates in paragraphs 1, 3, 4, and 5 by which actions must be taken to fulfill EPA's obligations under this Agreement.
7. If EPA fulfills the obligations described in paragraphs 1, 3, 4, and 5 by the dates described therein, or as modified pursuant to paragraph 6, the Parties will file a joint stipulation of dismissal of the petition for review within 14 calendar days following EPA's fulfillment of the last obligation under this Agreement.
8. If EPA fails to perform the obligations described in paragraphs 1, 3, 4, and 5 by the dates described therein, or as modified pursuant to paragraph 6, ACC may file a motion to dissolve the stay of ACC's petition for review, and to request that a briefing schedule be set. EPA does not waive or limit any defense relating to such litigation. This shall be ACC's only remedy for EPA's failure to fulfill its obligations under this Agreement. The Parties agree that contempt of court is not an available remedy under this Agreement.
9. If EPA performs the obligations described in paragraphs 1, 3, 4, and 5 by the dates described therein, or as modified pursuant to paragraph 6, this Agreement will constitute a full and final resolution of all matters related to the petition for review. ACC agrees to release, discharge, and covenant not to assert (by way of the commencement of an action, the joinder of EPA in an existing action, or in any other fashion) any and all claims, causes of action, suits or demands of any kind whatsoever in law or in equity which they

may have had, or may now or hereafter have, against EPA relating to the Final Rule. This Agreement becomes final when signed by the Parties.

10. No provision of this Agreement shall be interpreted as or constitute a commitment or requirement that the United States or any of its departments or agencies obligate or pay funds in contravention of the Anti-Deficiency Act, 31 U.S.C. § 1341 *et seq.*, or in violation of any other statute, law, or regulation. In the event that sufficient appropriated funding is not available, ACC's sole and exclusive remedy under this Settlement Agreement is set forth in paragraph 8. If a lapse in appropriations occurs within sixty days prior to the deadlines in paragraphs 1, 3, 4, and 5 of this Settlement Agreement, such deadlines shall be extended automatically one day for each day of the lapse in appropriations. Nothing in this paragraph shall preclude EPA from seeking an additional extension through modification of this Agreement pursuant to paragraph 6.
11. Nothing in this Agreement shall be construed to limit or modify the discretion accorded to EPA by statute, or by general principles of administrative law.
12. This Agreement shall not constitute an admission or evidence of any fact, wrongdoing, misconduct, or liability on the part of the United States, its officers, or any person affiliated with it.
13. Each party will bear its own costs of litigation.
14. This Agreement is the entire agreement between ACC and EPA for the issues involved in this case. All prior conversations, meetings, discussions, drafts and writings of any kind regarding issues involved in this case are specifically superseded by this Agreement. However, by email exchange dated \*\*\*, the Parties agree that the issues identified and described in that email exchange are not "issues involved in this case," and therefore will not be the subject of further litigation if ACC seeks to reopen the case pursuant to paragraph 8. The Parties agree that the issues identified and described in that email exchange are, however, covered by paragraph 9.
15. It is hereby expressly understood and agreed that this Agreement was jointly drafted by ACC and EPA. Accordingly, the Parties hereby agree that any and all rules of construction to the effect that ambiguity is construed against the drafting Party shall be inapplicable in any dispute concerning the terms, meaning, or interpretation of this Agreement.
16. The undersigned counsel for ACC and EPA hereby certify that they are duly authorized to bind their clients to the terms of this Agreement.

17. The provisions of this Agreement shall apply to and be binding on the Parties, their successors and assigns.
18. This Agreement may be signed in counterparts, and such counterpart signatures shall be given full force and effect.

FOR PETITIONER AMERICAN CHEMISTRY COUNCIL, INC.:

Dated: \_\_\_\_\_

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FOR RESPONDENT U.S. ENVIRONMENTAL PROTECTION AGENCY:

SAM HIRSCH  
Acting Assistant Attorney General  
Environment and Natural Resources Division

Dated: \_\_\_\_\_

By: \_\_\_\_\_

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